

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing statements of the quantity of the contents; Section 502 (f) (1), the repackaged drugs failed to bear adequate directions for use since the directions "One at bedtime as needed" borne on the labeling of the *Nembutal Sodium capsules* were not adequate directions for use and since the *sulfadiazine tablets* bore no labeling containing directions for use; and, Section 502 (b) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the *Nembutal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the tablets; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: March 27, 1951. A plea of guilty having been entered, the court imposed a fine of \$200 against the defendant.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3413. Adulteration and misbranding of citrate of magnesia. U. S. v. 84 Cases
* * * (F. D. C. No. 30437. Sample No. 47091-L.)

LABEL FILED: February 15, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about December 21, 1950, by the Pacific Coast Drug & Chemical Co., from Los Angeles, Calif.

PRODUCT: 84 cases, each containing 24 bottles, of *citrate of magnesia* at Phoenix, Ariz.

LABEL, IN PART: (Bottle) "Pasteurized Solution of Citrate of Magnesia U. S. P.
* * * National Magnesia Co. Inc., Brooklyn, N. Y. Contents 340 CC."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Magnesium Citrate Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength was less than that which the standard set forth in such compendium since each 100 cc. contained magnesium citrate equal to not more than 1.4 gm. of MgO and contained not more than 8.02 gm. of total citric acid. The standard provides that magnesium citrate solution contains in each 100 cc. a sufficient amount of magnesium citrate to equal 1.6 gm. of MgO, and further provides that each 100 cc. of such solution shall contain not less than 9.10 gm. of total citric acid.

Misbranding, Section 502 (a), the label statement "Solution of Citrate of Magnesia U. S. P." was false and misleading as applied to an article which was not the U. S. P. product.

DISPOSITION: April 25, 1951. Default decree of condemnation and destruction.